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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,544	05/10/2001	Miguel S. Barbosa	10624-051	7460
20583	7590	11/02/2004	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			PAK, MICHAEL D	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 11/02/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/853,544	BARBOSA ET AL.	
	Examiner	Art Unit	
	Michael Pak	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-16 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-16 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1646

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11 August 2004 has been entered.

Response to Amendment

2. The amendment filed 11 August 2004 has been entered. Claims 1-12 and 17-25 have been cancelled. Claims

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Applicant's arguments filed 11 August 2004, have been fully considered but they are not found persuasive.

Claim Rejections - 35 USC § 112

5. Claims 13-16 and 26 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

Art Unit: 1646

to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a written description rejection.

The reason for the rejection has been set forth in the previous office action.

Newly submitted claims 26 limitation to "breast cells" which does not overcome the rejection because claim 16 has the same limitations.

Applicants argue that a specification that discloses the specific nucleotide sequence which satisfies the written description requirement. However, essential feature of the claimed method is the discovery that nucleic acid sequences which have not been identified by function (i.e. orphan proteins) such as SEQ ID NO:1 can be used as regulated sequence of the estrogen modulation but the function of SEQ ID NO:1 is not known. For example at the time of the invention, NCI-CGAP (accession number AA747315, 1999), discloses a nucleic acid sequence which is identical to the claimed SEQ ID NO:1 but NCI-CGAP is a sequence which resulted from human genome sequencing and the function of the sequence is not known. Orphan proteins whose function is not known. Thus, the disclosure of an orphan nucleic sequence is not sufficient disclosure where the function of the protein or nucleic acid is known.

Applicants argue that the specification describes several species to provide description for a genus and therefore meets the standard established for adequate written description of sequences by the Federal Circuit. However, essential feature of the claimed method is the discovery of nucleic acid sequences which have not been identified by function such SEQ ID NO:1 can be used as regulated sequence of the estrogen modulation but the function of SEQ ID NO:1 is not known. For example at the

Art Unit: 1646

time of the invention, NCI-CGAP (accession number AA747315, 1999), discloses a nucleic acid sequence which is identical to the claimed SEQ ID NO:1 but NCI-CGAP is a sequence which resulted from human genome sequencing and the function of the sequence is not known. There is lack of written description for a method for genus of nucleic acid whose function is not known. The ability to regulate the nucleic acid does not provide sufficient written description for the nucleic acid whose function is not known.

Claim Rejections - 35 USC § 102

6. Claims 13,15-17 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Mendelsohn et al.(US 5,728,534).

The reason for the rejection has been set forth in the previous office actions.

Newly submitted claims 26 limitation to "breast cells" has been discussed previously and is taught by Mendelsohn et al. (columns 2-3 and 10-11).

Applicants argue that Mendelsohn does not teach the method of identifying selective estrogen receptor modulators using at least one endogenously-expressed ERM in the cells. However, the claims are not limited to endogenously-expressed ERM in the cells because no such claim limitations are in the claims.

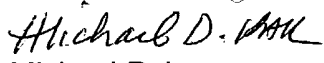
7. No claims are allowed.

Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached from 8:30 to 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Pak
Primary Patent Examiner
Art Unit 1646
26 October 2004